2009 H1N1 Vaccines

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Influenza Type A (H1N1 2009)

- A novel strain of influenza with genetic components of swine, avian and human viruses
- Little cross reactivity with previous H1N1 strains that have been circulating since 1977
- Epidemiology suggests that those born before 1957 may have some preexisting immunity

Influenza Prevention

- Vaccination is the single most important control measure we have

Time Line from Identification to Vaccine Production

Pandemic Strain Identified

Reassortant virus made (3-6 wks)

CDC/WHO confirm antigenic structure (3-6 wks)

Manufacture seed virus (3-12 wks)

FDA tests seed virus (1-2 weeks)

Potency testing (1-3 weeks)

Clinical trials 8-12 weeks

Formulate and release and test (3 wks)

Fill containers/package (3-6 wks)

Distribute Vaccine

28-40 weeks

Production of 2009 H1N1 Vaccine

- Vaccine production typically starts in January – so already 4 months behind AND manufacturing plants were already utilizing facilities for seasonal flu vaccine
- Manufacturing processes identical to seasonal influenza vaccine
- From the onset, FDA and ACIP recommended licensing the vaccine under the provisions of a “strain change”
- However, dosing for this novel strain was unclear

3 priority goals for Vaccine Trials

- 1 vs 2 doses looking at 15 ug and 30 ug
  - Prior flu studies suggested that 2 doses might be required since the 2009 H1N1 is so novel
  - Might also need a more potent vaccine

- Sequence of giving 2009 H1N1 with seasonal flu vaccine
  - Do the two vaccines adversely affect each other?

3 priority goals for Vaccine Trials

- 2009 H1N1 vaccine proteins given with adjuvant
  - Adjuvants are compounds that stimulate a faster and more robust immune response to the vaccine proteins
  - The US government has purchased two adjuvants – both have been used in influenza vaccines licensed in the EU
  - These adjuvants are not FDA approved in the U.S. so would have to be used under the Emergency Use Agreement

University of Iowa participation

- 2007 the U of I was selected as one of 8 Vaccine and Treatment Evaluation Units in the U.S. (7 year contract for $23 million)

- August 10, 2009: Started the first H1N1 trial
  - 1 vs 2 doses with CSL Ltd vaccine
  - 170 individuals (half 18-64; half 65+) enrolled in 10 days
  - Highest enrollment in the country
  - Volunteers from many parts of Iowa- Des Moines, Cedar Falls, Monticello, Mount Pleasant

Additional H1N1 Trials at U of I

- August 30, 2009: started pediatrics trial evaluating sequence of giving seasonal flu with H1N1 vaccine. 80 kids enrolled in 3 weeks
- September 10, 2009: Started adult trial assessing H1N1 vaccine with the adjuvant AS03. 130 screened to date

FDA Recommendations

- NIH data obtained within 4 weeks of trial initiation:
  - 1 dose of 15 ug will be sufficient for individuals 10 years and older.
  - Still awaiting more data for 3-9 yr olds.
  - 6mo-35 mo will need two doses
- Data pending on sequence of administration of H1N1 and seasonal flu vaccines, but in practicality seasonal flu will be available before H1N1.

Safety of Vaccines to Date: Expect safety to be similar to seasonal flu vaccines

- Observed Events for 2009 H1N1 Trials
  - Soreness at the injection site, mild flu-like illness
  - No unusual side effects have been identified

Estimated Supply of H1N1 2009 Influenza Vaccine

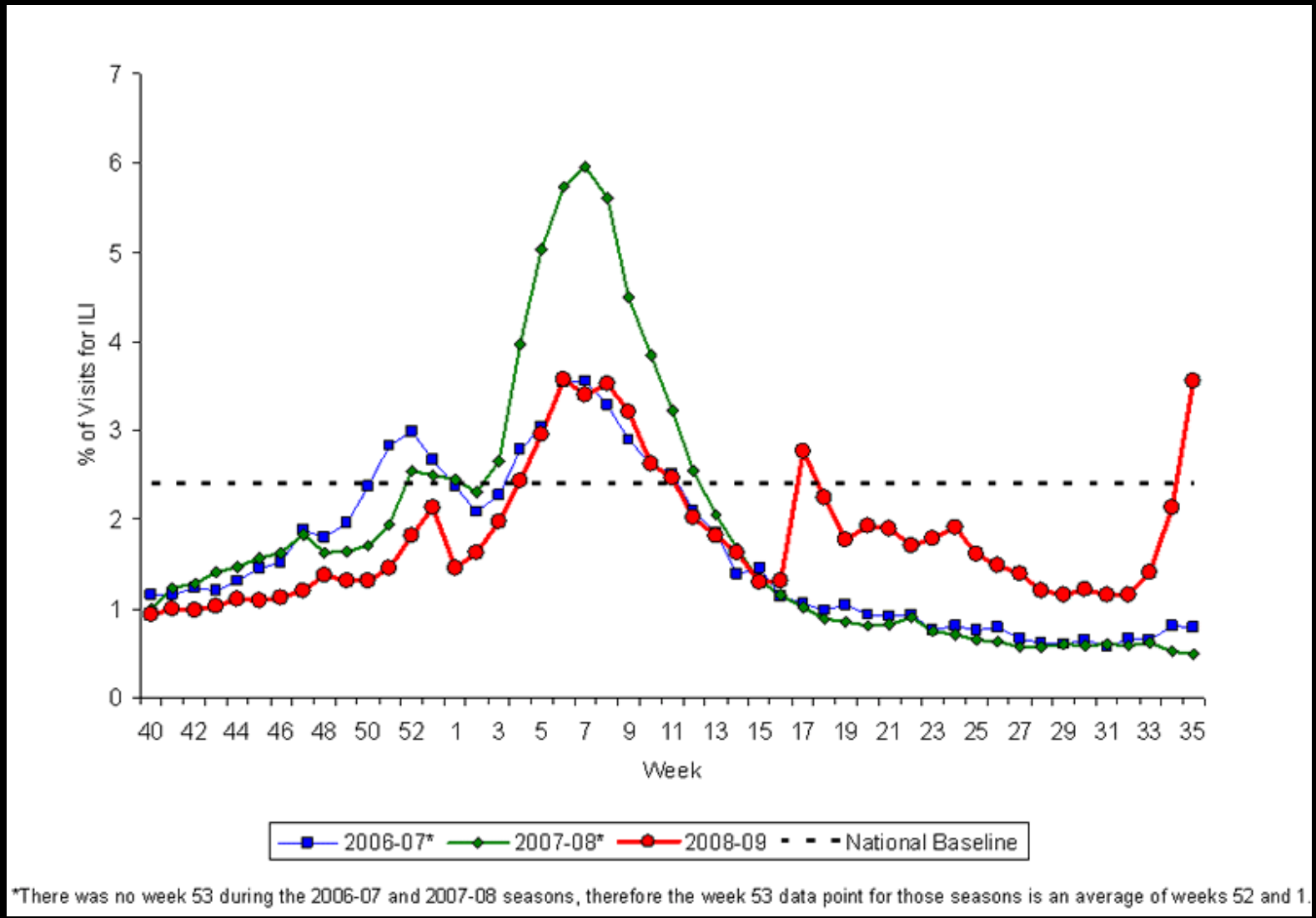
- ~300 million U.S. citizens
- TIV: 45 million doses by mid October followed by 20 million doses per week
- LAIV: 20 million doses (have virus stock for 100 million doses but supply of nasal spray bottle has been limited)
- At this time it seems unlikely that adjuvants will be used

Influenza Vaccine: H1N1 2009

- Vaccinate priority groups first
  - Ages 6mo-24 yr
  - Pregnant women
  - Health care personnel
  - Household contacts and caregivers of kids < 6mo
  - 24-64 yrs with chronic medical conditions

CDC: ACIP Recommendations

Race Against Time



CDC